# Complete Summary

## GUIDELINE TITLE

Guidelines for deep venous thrombosis prophylaxis during laparoscopic surgery.

## BIBLIOGRAPHIC SOURCE(S)

Society of American Gastrointestinal Endoscopic Surgeons (SAGES). Guidelines for deep venous thrombosis prophylaxis during laparoscopic surgery. Los Angeles (CA): Society of American Gastrointestinal Endoscopic Surgeons (SAGES); 2006 Oct. 6 p. [20 references]

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Society of American Gastrointestinal Endoscopic Surgeons (SAGES). Global statement on deep venous thrombosis prophylaxis during laparoscopic surgery. SAGES position statement. Surg Endosc 1999 Feb;13(2):200.

## ** REGULATORY ALERT **

## FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse**: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.

## COMPLETE SUMMARY CONTENT

## SCOPE

### DISEASE/CONDITION(S)

Deep venous thrombosis with subsequent pulmonary embolism

### GUIDELINE CATEGORY

Prevention
Risk Assessment

### CLINICAL SPECIALTY

Surgery

### INTENDED USERS

Physicians

### GUIDELINE OBJECTIVE(S)

To assist surgeons in making decisions regarding deep vein thrombosis (DVT) prophylaxis when performing laparoscopic procedures

### TARGET POPULATION

Patients undergoing laparoscopic procedures

### INTERVENTIONS AND PRACTICES CONSIDERED

1. Risk stratification
2. Deep vein thrombosis (DVT) prophylaxis including
    - Unfractionated heparin (UH)
    - Low molecular weight heparin (LMWH)
    - Pneumatic compression devices (PCDs)
    - Combination therapy
    - Inferior vena cava (IVC) filters
    - Compression stockings (considered but not recommended)
    - Coumadin (considered but not recommended)

### MAJOR OUTCOMES CONSIDERED

Not stated

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed a MEDLINE search.

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

**Levels of Evidence**

**Level I** - Evidence from properly conducted randomized, controlled trials

**Level II** - Evidence from controlled trials without randomization

**Or**

Cohort or case-control studies

**Or**

Multiple time series, dramatic uncontrolled experiments

**Level III** - Descriptive case series, opinions of expert panels

### METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Recommendations are based on the current medical evidence and have been graded according to the available evidence. Where data exist for only open surgical procedures, the guideline developers will adapt these data, and note a lower evidence and/or recommendation rating.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Each guideline is developed with a systematic approach, and includes review of the available literature and expert opinion when published data alone are insufficient to make recommendations.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

### Scale Used for Recommendation Grading

**Grade A** - Based on high-level (level I or II), well-performed studies with uniform interpretation and conclusions by the expert panel

**Grade B** - Based on high-level, well-performed studies with varying interpretation and conclusions by the expert panel

**Grade C** - Based on lower level evidence (level II or less) with inconsistent findings and/or varying interpretations or conclusions by the expert panel

## COST ANALYSIS

A published cost analyses was reviewed.

## METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This statement was reviewed and approved by the Board of Governors of the Society of American Gastrointestinal Endoscopic Surgeons (SAGES).

# RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

Levels of evidence (I–III) and recommendation grades (A–C) are defined at the end of the "Major Recommendations" field.

### Risk Stratification

### Operative Factors

Laparoscopic surgery of all types causes serum hypercoagualability of varying degrees (**level I, II evidence**). Shorter (less than one hour) and less complex laparoscopic procedures such as simple laparoscopic cholecystectomy probably have low risk of venous thromboembolism (VTE) disease (**level III evidence**). Longer/complex laparoscopic procedures such as laparoscopic roux-en-y gastric bypass are higher risk, (**level II evidence**). Although patient positioning may alter deep vein thrombosis (DVT) risk, there is not enough significant evidence to suggest that DVT prophylaxis should be changed based on body position alone.

**Patient Factors**

Age, immobility, history of venous thromboembolism, varicose veins, malignant disease, severe infection, chronic renal failure, more than three pregnancies, peri-pregnancy, congestive heart failure (CHF), history of myocardial infarction (MI), inflammatory bowel disease, hormone replacement therapy, oral contraceptive use, and obesity all increase risk (**level II evidence**). Inherited or acquired thrombophylias (e.g., protein C or S deficiency, factor V Leiden, antithrombin deficiency) greatly increase risk (**level II evidence**). A strong family history of clotting complications should be inquired about, and may also influence prophylactic treatment strategy.

**Table 1 – Risk Factors for VTE (One Point Each)**

| Procedure Specific | Patient Specific | |
|---|---|---|
| Duration >1 hour | History of VTE | Congestive heart failure |
| Pelvic procedure | Age >40 | Myocardial infarction |
| | Immobility | Hormone replacement therapy |
| | Varicose veins | Oral Contraceptive Use |
| | Cancer | Multiparity (3) |
| | Chronic renal failure | Inflammatory bowel disease |
| | Obesity | Severe infection |
| | Peri-partum | |
| For inherited or acquired thrombophilias hematology consult is recommended where available | | |

**Prophylactic Methods**

**Unfractionated Heparin (low dose UH)**

The dose is 5000 U given subcutaneously. This should be started within two hours of operation (**evidence level II**) and then every 8 or 12 hours. Every 8 hours is probably more effective at preventing VTE with similar risk of major bleeding (**level II evidence**). Continuous infusion of unfractionated heparin is as effective

as the subcutaneous route but has an increased risk of major bleeding and also requires hematologic monitoring (**level III evidence**).

**Low Molecular Weight Heparin (LMWH)**

The dose and frequency for LMWH depends on the manufacturer, and should be used according to their recommendations, although patient weight may also be a factor. One trial showed a need for increased LMWH in the morbidly obese (**level III evidence**). LMWH is at least as effective as low dose UH with a similar risk of major bleeding (**level I evidence**). There is decreased dosing schedule and decreased risk of heparin induced thrombocytopenia with LMWH compared to UH. Most studies start dosing the night before surgery with no other preoperative dosing to decrease the risk of operative bleeding. One trial showed no increase of operative bleeding when given two hours preoperatively versus the night before (**level I evidence**). Special consideration needs to be given when using LMWH with epidural or spinal anesthesia because of the risk of causing hematoma during placement or removal of the catheter (**level II evidence**).

**Pneumatic Compression Devices (PCD)**

Calf length pneumatic compression devices seem to offer the same protection for VTE as LMWH or low dose heparin (**level II evidence**). Foot pneumatic compression devices increase lower extremity venous blood flow and cause fibrinolysis to the same extent as calf length devices and seem to have similar benefit to calf length (**level III evidence**). Foot compression devices are often used with obese patients because calf length may not fit properly. With pneumatic compression devices there is no increased risk of bleeding and therefore little risk of use. There are no data to support the use of PCDs on only one extremity or the upper extremities during laparoscopic surgery.

**Combination Therapy**

LMWH or low dose UH with PCDs may decrease the risk of VTE even more than the single line therapy (**level II evidence**).

**Inferior Vena Cava (IVC) Filters**

These have been used for high risk patients—patients with venous stasis disease, body mass index (BMI) >59, truncal obesity, and hypoventilation syndrome, or sleep apnea undergoing Roux-en-Y gastric bypass with good results (**level III evidence**). There are retrievable filters that can be placed peri-operatively and removed up to a year later or left in place. If filters are left in place, low dose coumadin or equivalent anticoagulation is recommended to prevent IVC thrombosis and pulmonary embolism caused by the filter (**level III**).

**Compression Stockings, Coumadin**

These are inferior methods for the prevention of VTE (**level III evidence**). Presumably, compression stockings do not create enough pressure to prevent stasis in the deep leg veins or alter lower extremity blood flow and fibrinolysis.

The anticoagulative effect of coumadin alone starts too late to prevent DVT if given immediately prior to the surgical procedure.

**Table 2 - Suggested VTE Prophylaxis**

| Procedure | Risk Factors | Recommendation | Level of Recommendation Level of Evidence |
|---|---|---|---|
| Laparoscopic Cholecystectomy | 0 or 1 | None, PCDs, UH, or LMWH | **C; II, III** |
| Laparoscopic Cholecystectomy | 2 or more | PCDs, UH, or LMWH | **C; II, III** |
| Laparoscopic Appendectomy | 0 or 1 | None, PCDs, UH, or LMWH | **C; II, III** |
| Laparoscopic Appendectomy | 2 or more | PCDs, UH, or LMWH | **C; II, III** |
| Diagnostic Laparoscopy | 2 or more | PCDs, UH, or LMWH | **C; II, III** |
| Laparoscopic Inguinal Hernia | 2 or more | PCDs, UH, or LMWH | **C; II, III** |
| Laparoscopic Nissen Fundoplication | 0 or 1 | PCDs, UH, or LMWH | **B/II** |
| Laparoscopic Nissen Fundoplication | 2 or more | PCDs and UH or LMWH | **B/I, II** |
| Splenectomy | 0 or 1 | PCDs, UH, or LMWH | **B/II** |
| Splenectomy | 2 or more | PCDs and UH or LMWH | **B/II** |
| Other Major Laparoscopic Procedures: Roux-Y, etc | 0 or more | PCDs and UH or LMWH | **B/III** |

**Abbreviations**

- LMWH, low molecular weight heparin
- PCDs, pneumatic compression devices
- UH, unfractionated heparin

**Length of Treatment**

Length of treatment remains controversial. The guideline developers recommend treatment until patients are fully mobile or until discharge from the hospital, unless the patient has an acquired hypercoagulable state, then treatment for two weeks or more may be prudent (**level III**). Consultation with a hematologist may be helpful in determining an appropriate treatment strategy in these instances.

**Contraindications**

Contraindications to anticoagulation therapy for VTE prophylaxis will vary depending on the clinician's assessment of the risk-benefit ratio. The clinician should refer to individual manufacturer recommendations for specific therapy, and

utilize sound clinical judgment regarding the decision to withhold prophylactic therapy.

**Definitions**:

**Levels of Evidence**

**Level I** - Evidence from properly conducted randomized, controlled trials

**Level II** - Evidence from controlled trials without randomization

**Or**

Cohort or case-control studies

**Or**

Multiple time series, dramatic uncontrolled experiments

**Level III** - Descriptive case series, opinions of expert panels

**Recommendation Grading**

**Grade A** - Based on high-level (level I or II), well-performed studies with uniform interpretation and conclusions by the expert panel

**Grade B** - Based on high-level, well-performed studies with varying interpretation and conclusions by the expert panel

**Grade C** - Based on lower level evidence (level II or less) with inconsistent findings and/or varying interpretations or conclusions by the expert panel

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendation (see "Major Recommendations").

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Prevention of deep vein thrombosis during laparoscopic surgery

### POTENTIAL HARMS

### Heparin

- Unfractionated heparin (UH) and low molecular weight heparin (LMWH) are associated with the risk of major bleeding
- LMWH has a decreased risk of heparin induced thrombocytopenia compared with UH
- Special consideration needs to be given when using LMWH with epidural or spinal anesthesia because of the risk of causing hematoma during placement or removal of the catheter

### Inferior Vena Cava (IVC) Filters

If IVC filters are left in place, low dose coumadin or equivalent anticoagulation is recommended to prevent IVC thrombosis and pulmonary embolism caused by the filter.

## CONTRAINDICATIONS

### CONTRAINDICATIONS

Contraindications to anticoagulation therapy for VTE prophylaxis will vary depending on the clinician's assessment of the risk-benefit ratio.

## QUALIFYING STATEMENTS

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Clinical practice guidelines are intended to indicate the best available approach to medical conditions as established by systematic review of available data and expert opinion. The approach suggested may not necessarily be the only acceptable approach given the complexity of the health care environment. These guidelines are intended to be flexible, as the physician must always choose the approach best suited to the individual patient and variables in existence at the moment of decision. These guidelines are applicable to all physicians who are appropriately credentialed and address the clinical situation in question, regardless of specialty.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Society of American Gastrointestinal Endoscopic Surgeons (SAGES). Guidelines for deep venous thrombosis prophylaxis during laparoscopic surgery. Los Angeles (CA): Society of American Gastrointestinal Endoscopic Surgeons (SAGES); 2006 Oct. 6 p. [20 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

1999 (revised 2006 Oct)

### GUIDELINE DEVELOPER(S)

Society of American Gastrointestinal and Endoscopic Surgeons - Medical Specialty Society

### SOURCE(S) OF FUNDING

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

### GUIDELINE COMMITTEE

Committee on Standards of Practice

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Members of the Society of American Gastrointestinal and Endoscopic Surgeons disclose potential conflicts of interest and pertinent financial relationships prior to serving as faculty for SAGES-sponsored educational events, delivering presentations at scientific meetings, etc. Additionally, members of SAGES Committees disclose their potential conflicts of interest and pertinent financial relationships annually as a condition of committee membership.

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### GUIDELINE AVAILABILITY

Electronic copies: Available from the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Web site.

Print copies: Available from the Society of American Gastrointestinal Endoscopic Surgeons (SAGES), 11300 W. Olympic Blvd., Suite 600, Los Angeles, CA 90064; Web site: www.sages.org.

### AVAILABILITY OF COMPANION DOCUMENTS

None available

### PATIENT RESOURCES

None available

### NGC STATUS

This summary was completed by ECRI on November 19, 1999. The information was verified by the guideline developer on February 15, 2000. This NGC summary was updated by ECRI Institute on October 9, 2007. The updated information was verified by the guideline developer on October 29, 2007. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection.

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